

Substitute for Form 1449 A & B/PTO

Complete if Known

INFORMATION DISCLOSURE
STATEMENT BY APPLICANT

(use as many sheets as necessary)

| | |
|------------------------|----------------------|
| Application Number | 10/054,914 |
| Confirmation Number | 5596 |
| Filing Date | January 25, 2002 |
| First Named Inventor | Thomas S.Y. KO et al |
| Art Unit | 1619 |
| Examiner Name | Unknown |
| Attorney Docket Number | Q-68257 |

1 of 5

U.S. PATENT DOCUMENTS

| Examiner Initials* | Cite No. ¹ | Document Number | | Publication Date MM-DD-YYYY | Name of Patentee or Applicant of Cited Document |
|--------------------|-----------------------|-----------------|--------------------------------------|--------------------------------|---|
| | | Number | Kind Code ² (if known) | | |
| | | | | | |
| | | | | | |

FOREIGN PATENT DOCUMENTS

| Examiner Initials* | Cite No. ¹ | Foreign Patent Document | | | Publication Date MM-DD-YYYY | Name of Patentee or Applicant of Cited Document | Translation ⁶ |
|--------------------|-----------------------|---------------------------|---------------------|--------------------------------------|--------------------------------|---|--------------------------|
| | | Country Code ³ | Number ⁴ | Kind Code ⁵ (if known) | | | |
| JS | | AU | 78721/87 | | 03/24/1988 | Enzacor Properties, Ltd. | |
| | | AU | 23673/92 | | 02/23/1993 | Enzacor Properties, Ltd. | |
| | | | | | | | |

OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS

| Examiner Initials* | Cite No. ¹ | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city, and/or country where published. | Translation ⁶ |
|--------------------|-----------------------|--|--------------------------|
| JS | | Cleland et al, <i>Pharm. Res.</i> , 13(10):1464-1475 (1996) | Abstract |
| | | Cleland et al, <i>Pharm. Res.</i> , 14(4):420-425 (1997) | Abstract |
| | | Yang et al, <i>J. Pharm. Sci.</i> , 86(8):908-914 (1986) | Abstract |
| | | Johnson et al, <i>Pharm. Res.</i> , 14(6):730-735 (1997) | Abstract |
| | | Jones et al, <i>Adv. Drug Deliv. Rev.</i> , 28(1):71-84 (1997) | Abstract |
| | | Kim et al, <i>Biotechnol. Bioeng.</i> , 65(6):659-667 (1999) | Abstract |
| | | Carrasquillo et al, <i>J. Pharm. Sci.</i> , 88(2):166-173 (1999) | Abstract |
| | | Blanco et al, <i>Eur. J. Pharm. Biopharm.</i> , 45(3):285-294 (1998) | Abstract |
| | | Costantino et al, <i>J. Pharm. Sci.</i> , 87(11):1412-1420 (1998) | Abstract |
| | | Johnson et al, <i>Nat. Med.</i> , 2(7):795-799 (1996) | Abstract |
| | | Brodbeck et al, <i>Pharm. Res.</i> , 16(12):1825-1829 (1999) | Abstract |
| | | Sah et al, <i>PDA J. Pharm. Sci. Technol.</i> , 53(1):3-10 (1999) | Abstract |
| | | Park et al, <i>J. Controlled Release</i> , 55(2-3):181-191 (1988) | Abstract |
| | | Schwendeman et al, <i>J. Microencapsul.</i> , 15(3):299-318 (1998) | Abstract |
| | | Gupta et al, <i>Vaccine</i> , 15(6-7):672-678 (1997) | Abstract |
| | | Chang et al, <i>J. Pharm. Sci.</i> , 85(2):129-132 (1996) | Abstract |
| | | Alonso et al, <i>Pharm. Res.</i> , 10(7):945-953 (1993) | Abstract |
| | | Maa et al, <i>J. Pharm. Sci.</i> , 87(2):152-159 (1998) | Abstract |
| | | Shenderova et al, <i>Pharm. Res.</i> , 14(10):1406-1414 (1997) | Abstract |
| | | Uchida et al, <i>J. Microencapsul.</i> , 13(5):509-518 (1996) | Abstract |
| | | Uchida et al, <i>Chem. Pharm. Bull.</i> , 44(1):235-236 (1996) | Abstract |
| | | Lu et al, <i>PDA J. Pharm. Sci., Technol.</i> , 49(1):13-19 (1995) | Abstract |
| | | Cohen et al, <i>Pharm. Res.</i> , 8(6):713-720 (1991) | Abstract |
| | | Lam et al, <i>J. Controlled Release</i> , 67(2-3):281-292 (2000) | Abstract |
| | | Jain et al, <i>J. Microencapsul.</i> , 17(3):343-362 (2000) | Abstract |

Examiner Signature

JAMES M. SPEAR

Date Considered

06-24-2004

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). ² See Kinds Codes of USPTO Patent Documents at www.uspto.gov, MPEP 901.04 or in the comment box of this document. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST. 3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to indicate here if English language Translation is attached.

Substitute for Form 1449 A & B/PTO

Complete if Known

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(use as many sheets as necessary)

Sheet

2

of

5

| | |
|------------------------|----------------------|
| Application Number | 10/054,914 |
| Confirmation Number | 5596 |
| Filing Date | January 25, 2002 |
| First Named Inventor | Thomas S.Y. KO et al |
| Art Unit | 1619 |
| Examiner Name | Unknown |
| Attorney Docket Number | Q-68257 |

U.S. PATENT DOCUMENTS

| Examiner Initials* | Cite No. ¹ | Document Number | | Publication Date MM-DD-YYYY | Name of Patentee or Applicant of Cited Document |
|--------------------|-----------------------|-----------------|--------------------------------------|--------------------------------|---|
| | | Number | Kind Code ² (if known) | | |
| | | | | | |
| | | | | | |

FOREIGN PATENT DOCUMENTS

| Examiner Initials* | Cite No. ¹ | Foreign Patent Document | | | Publication Date MM-DD-YYYY | Name of Patentee or Applicant of Cited Document | Translation ⁶ |
|--------------------|-----------------------|---------------------------|---------------------|--------------------------------------|--------------------------------|---|--------------------------|
| | | Country Code ³ | Number ⁴ | Kind Code ⁵ (if known) | | | |
| | | | | | | | |
| | | | | | | | |

OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS

| Examiner Initials* | Cite No. ¹ | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city, and/or country where published. | Translation ⁶ |
|--------------------|-----------------------|--|--------------------------|
| | | Tracy, <i>Biotechnol. Prog.</i> , 14(1):108-115 (1998) | Abstract |
| | | Tzannis et al, <i>J. Pharm. Sci.</i> , 88(3):351-359 (1999) | Abstract |
| | | Katakam et al, <i>Pharm. Dev. Technol.</i> , 2(2):143-149 (1997) | Abstract |
| | | Schwendeman et al, <i>Dev. Biol. Stand.</i> , 87:293-306 (1996) | Abstract |
| | | Cleland, <i>Pharm. Biotechnol.</i> , 10:1-43 (1997) | Abstract |
| | | Okada et al, <i>Crit. Rev. Ther. Drug Carrier Syst.</i> , 12(1):1-99 (1995) | Abstract |
| | | Alonso et al, <i>Vaccine</i> , 12(4):299-306 (1994) | Abstract |
| | | Leo et al, <i>J. Microcapsul.</i> , 15(4):421-430 (1998) | Abstract |
| | | Putney, <i>Curr. Opin. Chem. Biol.</i> , 2(4):548-552 (1998) | Abstract |
| | | Lam et al, <i>Pharm. Res.</i> , 14(6):725-729 (1997) | Abstract |
| | | Takada et al, <i>PDA J. Pharm. Sci. Technol.</i> , 49(4):180-184 (1995) | Abstract |
| | | Sato et al, <i>Pharm. Res.</i> , 5(1):21-30 (1988) | Abstract |
| | | Pikal et al, <i>Pharm. Res.</i> , 8(4):427-436 (1991) | Abstract |
| | | Costantino et al, <i>J. Pharm. Sci.</i> , 87(11):1406-1411 (1988) | Abstract |
| | | Torres et al, <i>J. Microcapsul.</i> , 13(1):41-51 (1996) | Abstract |
| | | Prestrelski et al, <i>Arch Biochem. Biophys.</i> , 303(2):465-473 (1993) | Abstract |
| | | Hellebust et al, <i>Biotechnol Appl. Biochem.</i> , 18(Pt 3):227-237 (1993) | Abstract |
| | | Zhu et al, <i>Pharm. Res.</i> , 17(3):351-357 (2000) | Abstract |
| | | Maa et al, <i>Pharm. Dev. Technol.</i> , 2(3):213-223 (1997) | Abstract |
| | | Zhang et al, <i>Pharm. Res.</i> , 12(10):1447-1452 (1995) | Abstract |
| | | Iwata et al, <i>Pharm. Res.</i> , 10(8):1219-1227 (1993) | Abstract |
| | | Heya et al, <i>J. Pharm. Sci.</i> , 83(5):636-640 (1994) | Abstract |
| | | Mumenthaler et al, <i>Pharm. Res.</i> , 11(1):12-20 (1994) | Abstract |
| | | Maharaj et al, <i>J. Pharm. Res.</i> , 73(1):39-42 (1984) | Abstract |
| | | Alex et al, <i>J. Microencapsul.</i> , 7(3):347-355 (1990) | Abstract |

Examiner Signature

JAMES M. SPEAR

Date Considered

06-26-2004

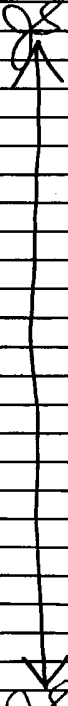
*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹Applicant's unique citation designation number (optional). ²See Kinds Codes of USPTO Patent Documents at www.uspto.gov, MPEP 901.04 or in the comment box of this document. ³Enter Office that issued the document, by the two-letter code (WIPO Standard ST. 3). ⁴For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶Applicant is to indicate here if English language Translation is attached.

| | | | | |
|---|--|--|------------------------|----------------------|
| Substitute for Form 1449 A & B/PTO | | | Complete if Known | |
| INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary) Sheet <u>3</u> of <u>5</u> | | | Application Number | 10/054,914 |
| | | | Confirmation Number | 5596 |
| | | | Filing Date | January 25, 2002 |
| | | | First Named Inventor | Thomas S.Y. KO et al |
| | | | Art Unit | 1619 |
| | | | Examiner Name | Unknown |
| | | | Attorney Docket Number | Q-68257 |

| U.S. PATENT DOCUMENTS | | | | | |
|-----------------------|-----------------------|-----------------|--------------------------------------|--------------------------------|---|
| Examiner Initials* | Cite No. ¹ | Document Number | | Publication Date MM-DD-YYYY | Name of Patentee or Applicant of Cited Document |
| | | Number | Kind Code ² (if known) | | |
| | | | | | |
| | | | | | |
| | | | | | |

| FOREIGN PATENT DOCUMENTS | | | | | | | |
|--------------------------|-----------------------|---------------------------|---------------------|--------------------------------------|--------------------------------|---|--------------------------|
| Examiner Initials* | Cite No. ¹ | Foreign Patent Document | | | Publication Date MM-DD-YYYY | Name of Patentee or Applicant of Cited Document | Translation ⁶ |
| | | Country Code ³ | Number ⁴ | Kind Code ⁵ (if known) | | | |
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |

| OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS | | | |
|--|-----------------------|--|--------------------------|
| Examiner Initials* | Cite No. ¹ | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city, and/or country where published. | Translation ⁶ |
|  | | Kendrick et al, <i>Proc. Natl. Acad. Sci. USA</i> , <u>95</u> (24):14142-14146 (1998) | Abstract |
| | | Uchida et al, <i>J. Pharm. Pharmacol.</i> , <u>47</u> (7):556-560 (1995) | Abstract |
| | | Sanghvi et al, <i>J. Microencapsul.</i> , <u>10</u> (2):181-194 (1993) | Abstract |
| | | Arakawa et al, <i>Biopolymers</i> , <u>29</u> (6-7):1065-1068 (1990) | Abstract |
| | | Johansen et al, <i>Eur. J. Pharm. Biopharm.</i> , <u>47</u> (3):193-201 (1999) | Abstract |
| | | Pikal et al, <i>Dev. Biol. Stand.</i> , <u>74</u> :21-37 (1992) | Abstract |
| | | Tzannis et al, <i>J. Pharm. Sci.</i> , <u>88</u> (3):360-370 (1999) | Abstract |
| | | Uchida et al, <i>J. Microencapsul.</i> , <u>13</u> (2):219-228 (1996) | Abstract |
| | | Tabata et al, <i>Pharm. Res.</i> , <u>10</u> (4):487-496 (1993) | Abstract |
| | | Gander et al, <i>J. Microencapsul.</i> , <u>12</u> (1):83-97 (1995) | Abstract |
| | | Hora et al, <i>Pharm. Res.</i> , <u>7</u> (11):1190-1194 (1990) | Abstract |
| | | Oroszlan et al, <i>Anal. Chem.</i> , <u>64</u> (14):1623-1631 (1992) | Abstract |
| | | Green et al, <i>Toxicol. Lett.</i> , <u>64-65</u> :Spec. No. 321-327 (1992) | Abstract |
| | | Pavlu et al, <i>Bioseparation</i> , <u>3</u> (5):257-265 (1992-1993) | Abstract |
| | | Andya et al, <i>Pharm. Res.</i> , <u>16</u> (3):350-358 (1999) | Abstract |
| | | Hayes et al, <i>Biotechnol. Bioeng.</i> , <u>59</u> (5):557-566 (1998) | Abstract |
| | | Eyles et al, <i>J. Pharm. Pharmacol.</i> , <u>49</u> (7):669-674 (1997) | Abstract |
| | | Heelan et al, <i>J. Microencapsul.</i> , <u>14</u> (1):63-78 (1997) | Abstract |
| | | Di Silvio et al, <i>Biomaterials</i> , <u>15</u> (11):931-936 (1994) | Abstract |
| | | Arakawa et al, <i>Biochemistry</i> , <u>29</u> (7):1914-1923 (1990) | Abstract |
| | | Wan et al, <i>J. Microencapsul.</i> , <u>9</u> (3):309-316 (1992) | Abstract |
| | | Bam et al, <i>J. Pharm. Sci.</i> , <u>87</u> (12):1554-1559 (1998) | Abstract |
| | | Leuckel et al, <i>Pharm. Dev. Technol.</i> , <u>3</u> (3):337-346 (1998) | Abstract |
| | | Carpenter et al, <i>Arch Biochem. Biophys.</i> , <u>303</u> (2):456-464 (1993) | Abstract |
| | | Pongpaibul et al, <i>J. Pharm. Pharmacol.</i> , <u>40</u> (8):530-533 (1988) | Abstract |

| | | | |
|--------------------|----------------|-----------------|------------|
| Examiner Signature | JAMES M. SPEAR | Date Considered | 06-26-2004 |
|--------------------|----------------|-----------------|------------|

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹Applicant's unique citation designation number (optional). ²See Kinds Codes of USPTO Patent Documents at www.uspto.gov, MPEP 901.04 or in the comment box of this document. ³Enter Office that issued the document, by the two-letter code (WIPO Standard ST. 3). ⁴For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶Applicant is to indicate here if English language Translation is attached.

Substitute for Form 1449 A & B/PTO

Complete if Known

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

Use as many sheets as necessary)

Sheet 4 of 5

| | |
|------------------------|----------------------|
| Application Number | 10/054,914 |
| Confirmation Number | 5596 |
| Filing Date | January 25, 2002 |
| First Named Inventor | Thomas S.Y. KO et al |
| Art Unit | 1619 |
| Examiner Name | Unknown |
| Attorney Docket Number | Q-68257 |

U.S. PATENT DOCUMENTS

| Examiner Initials* | Cite No. ¹ | Document Number | | Publication Date MM-DD-YYYY | Name of Patentee or Applicant of Cited Document |
|--------------------|-----------------------|-----------------|--------------------------------------|--------------------------------|---|
| | | Number | Kind Code ² (if known) | | |
| | | | | | |
| | | | | | |

FOREIGN PATENT DOCUMENTS

| Examiner Initials* | Cite No. ¹ | Foreign Patent Document | | | Publication Date MM-DD-YYYY | Name of Patentee or Applicant of Cited Document | Translation ⁶ |
|--------------------|-----------------------|---------------------------|---------------------|--------------------------------------|--------------------------------|---|--------------------------|
| | | Country Code ³ | Number ⁴ | Kind Code ⁵ (if known) | | | |
| | | | | | | | |
| | | | | | | | |

OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS

| Examiner Initials* | Cite No. ¹ | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city, and/or country where published. | Translation ⁶ |
|--------------------|-----------------------|--|--------------------------|
| JS | | Iwata et al, <i>J. Microencapsul.</i> , 9(2):201-214 (1992) | Abstract |
| | | Vudathala et al, <i>Pharm. Res.</i> , 9(6):759-763 (1992) | Abstract |
| | | Huatan et al, <i>J. Microencapsul.</i> , 12(5):557-567 (1995) | Abstract |
| | | Chen et al, <i>J. Microencapsul.</i> , 11(4):395-407 (1994) | Abstract |
| | | Uchida et al, <i>Biol. Pharm. Bull.</i> , 17(9):1272-1276 (1994) | Abstract |
| | | Short et al, <i>Pharm. Res.</i> , 12(8):1140-1145 (1995) | Abstract |
| | | Margalit et al, <i>J. Microencapsul.</i> , 2(3):183-196 (1985) | Abstract |
| | | Jones et al, <i>J. Pharm. Pharmacol.</i> , 41(12):813-816 (1989) | Abstract |
| | | Costantino et al, <i>Biotechnology</i> , 13(5):493-496 (1995) | Abstract |
| | | Ma et al, <i>J. Drug Target</i> , 2(1):9-21 (1994) | Abstract |
| | | Bindschaedler et al, <i>J. Pharm. Sci.</i> , 77(8):696-698 (1988) | Abstract |
| | | Page et al, <i>J. Pharm. Pharmacol.</i> , 52(1):19-26 (2000) | Abstract |
| | | Duddu et al, <i>Pharm. Res.</i> , 14(5):591-595 (1997) | Abstract |
| | | Anchordoquy et al, <i>Arch. Biochem. Biophys.</i> , 332(2):231-238 (1996) | Abstract |
| | | Sah et al, <i>Pharm. Res.</i> , 13(3):360-367 (1996) | Abstract |
| | | Tsai et al, <i>Pharm. Res.</i> , 10(5):649-659 (1993) | Abstract |
| | | Gekko et al, <i>Biochemistry</i> , 20(16):4667-4776 (1981) | Abstract |
| | | Tabata et al, <i>Pharm. Res.</i> , 6(5):422-427 (1989) | Abstract |
| | | Kita et al, <i>Drug. Des. Deliv.</i> , 6(3):157-167 (1990) | Abstract |
| | | Hora et al, <i>Pharm. Res.</i> , 9(1):33-36 (1992) | Abstract |
| | | Costantino et al, <i>J. Pharm. Sci.</i> , 86(12):1390-1393 (1997) | Abstract |
| | | Cedrat et al, <i>Artif. Cells Blood Substit. Immobil. Biotechnol.</i> , 22(3):867-873 (1994) | Abstract |
| | | Weiner et al, <i>Immunomethods</i> , 4(3):201-209 (1994) | Abstract |
| | | Sah et al, <i>J. Microencapsul.</i> , 12(1):59-69 (1995) | Abstract |
| | | Shukla et al, <i>Pharm. Res.</i> , 6(5):418-421 (1989) | Abstract |

Examiner Signature

JAMES M. SPEAR

Date Considered

06-26-2004

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹Applicant's unique citation designation number (optional). ²See Kinds Codes of USPTO Patent Documents at www.uspto.gov, MPEP 901.04 or in the comment box of this document. ³Enter Office that issued the document, by the two-letter code (WIPO Standard ST. 3). ⁴For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶Applicant is to indicate here if English language Translation is attached.

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

Sheet

4

of 5

| | |
|------------------------|----------------------|
| Application Number | 10/054,914 |
| Confirmation Number | 5596 |
| Filing Date | January 25, 2002 |
| First Named Inventor | Thomas S.Y. KO et al |
| Art Unit | 1619 |
| Examiner Name | Unknown |
| Attorney Docket Number | Q-68257 |

| Examiner Initials* | Cite No. ¹ | Document Number | | Publication Date MM-DD-YYYY | Name of Patentee or Applicant of Cited Document |
|--------------------|-----------------------|-----------------|--------------------------------------|--------------------------------|---|
| | | Number | Kind Code ² (if known) | | |
| | | | | | |
| | | | | | |

| Examiner Initials* | Cite No. ¹ | Foreign Patent Document | | | Publication Date MM-DD-YYYY | Name of Patentee or Applicant of Cited Document | Translation ⁶ |
|--------------------|-----------------------|---------------------------|---------------------|--------------------------------------|--------------------------------|--|--------------------------|
| | | Country Code ³ | Number ⁴ | Kind Code ⁵ (if known) | | | |
| | | | | | | | |
| | | | | | | | |

[illegible]

JAMES M. SPEAR

Date Considered

06-26-2004

¹ Applicant's unique citation designation number (optional). ² See Kinds Codes of USPTO Patent Documents at www.uspto.gov, MPEP 901.04 or in the comment box of this document. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST. 3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to indicate here if English language Translation is attached.

| | | | | | |
|---|---|----|----------------------|------------------------|--------|
| Substitute for Form 1449 A & B/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary) | | | COMPLETE IF KNOWN | | |
| | | | Application Number | 10/054,914 | |
| | | | Confirmation Number | 5596 | |
| | | | Filing Date | January 25, 2002 | |
| | | | First Named Inventor | Thomas S.Y. KO et al. | |
| | | | Art Unit | 1619 | |
| | | | Examiner Name | Unknown | |
| Sheet | 1 | of | 1 | Attorney Docket Number | Q68257 |

U.S. PATENT DOCUMENTS

| Examiner Initials* | Cite No. ¹ | Document Number | | Publication Date MM-DD-YYYY | Name of Patentee or Applicant of Cited Document |
|-----------------------|--------------------------|-----------------|--------------------------------------|--------------------------------|---|
| | | Number | Kind Code ² (if known) | | |
| | | | | | |
| | | | | | |
| | | | | | |
| | | | | | |
| | | | | | |
| | | | | | |
| | | | | | |
| | | | | | |
| | | | | | |

FOREIGN PATENT DOCUMENTS

| Examiner Initials* | Cite No. ¹ | Foreign Patent Document | | | Publication Date MM-DD-YYYY | Name of Patentee or Applicant of Cited Document | Translation ⁶ |
|-----------------------|--------------------------|------------------------------|---------------------|--------------------------------------|--------------------------------|--|--------------------------|
| | | Country Code ³ | Number ⁴ | Kind Code ⁵ (if known) | | | |
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |

OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS

| Examiner Initials* | Cite No. ¹ | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city, and/or country where published. | Translation ⁶ |
|-----------------------|--------------------------|--|--------------------------|
| JS | | Charman et al, <i>J. Pharm. Sci.</i> , 89:168-177 (2000) | |
| JS | | McLennan et al, "Molecular Weight is a Primary Determinant for Lymphatic Absorption of Proteins Following Subcutaneous Administration", Podium Session 4, Paper 5, <i>Proceedings of the Australasian Pharmaceutical Science Association, Annual Conference 2001</i> | |
| JS | | Okada et al, <i>Crit. Rev. Ther. Drug Carrier Syst.</i> , 12(1):1-99 (1995) | Abstract |
| | | | |
| | | | |
| | | | |

| | | | |
|--------------------|----------------|-----------------|------------|
| Examiner Signature | JAMES M. SPEAR | Date Considered | 06-24-2004 |
|--------------------|----------------|-----------------|------------|

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹Applicant's unique citation designation number (optional). ²See Kind Codes of USPTO Patent Documents at www.uspto.gov, MPEP 901.04 or in the comment box of this document. ³Enter Office that issued the document, by the two-letter code (WIPO Standard ST. 3). ⁴For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶Applicant is to indicate here if English language Translation is attached.

[illegible][illegible]

| OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS | | | |
|---|-----------------------|--|--------------------------|
| Examiner Initials* | Cite No. ¹ | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city, and/or country where published. | Translation ⁶ |
| JS | | Porter et al, <i>Adv. Drug Del. Rev.</i> , <u>50</u> :157-171 (2001) | |
| | | Porter et al, <i>J. Pharm. Sci.</i> , <u>89</u> (3):297-310 (2000) | |
| | | | |
| | | | |
| | | | |

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹Applicant's unique citation designation number (optional). ²See Kind Codes of USPTO Patent Documents at www.uspto.gov, MPEP 901.04 or in the comment box of this document. ³Enter Office that issued the document, by the two-letter code (WIPO Standard ST. 3). ⁴For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶Applicant is to indicate here if English language Translation is attached.